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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,315	10/23/2001	Hugh Semple Munro	740150/52050-C	9422

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NIXON PEABODY LLP
ATTENTION: DAVID RESNICK
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,315

Applicant(s)

MUNRO ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-15, 17-20, 22, 24-38, 40-43, 45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-15, 17-20, 22, 24-38, 40-43, and 45-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Receipt of Amendments and Remarks received on April 1, 2004 is acknowledged. Claims **1-6, 9-15, 17-20, 22, 24-38, 40-43, and 45-46** are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9-10, 12-15, 17-20, 22, 24-31, 42-43, and 45-46 are rejected under 35

U.S.C. 103(a) as being unpatentable over Cheong (5,352,508) in view of Jensen (5,133,821).

Cheong discloses a net wound dressing wherein a hydrophilic resin is coated on a substrate without occlusion (abstract). The resin is a polymerized hydrogel or crosslinked polyurethane resin (column 3). Suitable substrates are woven and non-woven materials such as polyamide, polypropylene, cotton, rayon, or wool (col. 5, lines 1-3). The amount of resin coated on the substrate is 25-300 g/m². The resin is applied to coating rollers and coated on to the

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substrate, which then undergoes heating to cure the resin (col. 5, lines 20-25 and example 5). In example 1, the reference teaches coating one side of the substrate.

Cheong does not teach a coated web.

Jensen teaches a method of making wound dressing wherein the gel is placed between a release paper (coated web) and a substrate and extruded via a rolling process. Jensen teaches a release coating on one of its surfaces minimizes the friction generated during the rolling process. The reference teaches the preferred release web is silicone paper which is removed after the rolling process. (Note col. 3, lines 53-65). Jensen also teaches a protective release covering which is removed upon use (Figure 3, 32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Cheong and Jensen. One would be motivated to do so since Jensen teaches a release coating minimizes friction generated during the rolling process. Thus, since Cheong and Jensen utilize the same rolling process, one would be motivated to use a paper coated with silicone to increase efficacy during the process of making the dressing. Further, Jensen teaches that the web prevents the gel from being transferred to the roller during manufacturing and Cheong discusses the problem of the resin sticking to the rollers on column 5.

Response to Arguments

Applicant argues that Cheong does not teach a coated web with a low surface energy. Applicant argues that while Cheong teaches a nonocclusive gel, Cheong does so by a different manner than the instant invention. Further, applicant argues that Cheong encapsulates the substrate and instant invention does not and then blows air thorough the substrate pores to remove the blockage. It is argued that Jensen does not teach or suggest the invention at all.

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Firstly the examiner points out that although Cheong encapsulates the perforated substrate to provide for a product with two tacky surfaces, the rejected claims do not specify that the instant product is not encapsulated. The limitation that the substrate is coated only one side is not sufficient to overcome this since Cheong's example 1 also teaches coating only one side. Secondly, the examiner notes column 5 wherein Cheong states that the coated substrate may be blasted with air to reopen the apertures that may have been occluded. However, the examiner first points out that Cheong states that this is optional, therefore clearly even without this step the majority of the apertures are unoccluded. It further pointed out that the instant claims do not exclude this step.

In regards to Jensen, the examiner points out that clearly Jensen teaches the instant coated web (silicon coated paper) for the same extrusion process utilized in Cheong. Jensen states the silicone paper reduces friction during the process. It should also be noted that Cheong states that sheets of plastic inherently and silicon treated paper inherently have low tack for the resin used. See column 5, lines 52-58. The prior art does not have to show all the results obtainable by the disclosed prior art process, i.e. the use of the coated web, it merely has to show that the process is within the skill of the art. The applicant has not provided any distinguishable limitation to impart this distinct property to the instant claims. Since the prior art shows the instant steps, the process per say is deemed obvious.

Claims 11, 32-38, and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheong (5,352,508) in view of Jensen (5,133,821) in further view of Kundel (5,674,346).

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As set forth above, Cheong and Jensen teach wound dressings and a process of making the wound dressing.

The references do not teach a gel containing acrylate monomer.

Kundel teaches a hydrogel wound dressing. Kundel teaches conventional polymers such as acrylates that form the hydrogel (col. 4, lines 30-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Cheong and Kundel since both teach hydrophilic wound dressings. One would be motivated to look to Kundel since the reference teaches the conventional use of acrylates in wound dressing compositions. Therefore, it is deemed obvious to use conventional gel materials with the expectation of similar results.

Response to Arguments

Applicant has not specifically addressed this rejection.

Claims 1-6, 9-10, 12, 15, 17-20, 24-31, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/42985 in view of Jensen (5,133,821).

WO discloses a wound dressing and the method of making it. The method includes placing a gel mixture of polymers on a thin plastic film (web) and applying a foam layer (the perforated substrate) to the uncured gel mixture with the aid of a roller. The substrate and the gel are placed in the oven to cure the gel mixture. The gel coating should not block the pores of the substrate, thus the gel is applied in a thickness of 0.1-1 mm and the total gel layer has thickness of 0.2-2 mm. See page 9. The gel layer is a chemically cross-linked silicone gel (page 5).

WO does not specify teach a coating on the plastic film, or a release sheet.

Jensen teaches a method of making wound dressing wherein the gel is placed between a release paper (coated web) and a substrate and extruded via a rolling process. Jensen teaches a release coating on one of its surfaces minimizes the friction generated during the rolling process. The reference teaches the preferred release web is silicone paper, which is removed after the rolling process. (Note col. 3, lines 53-65). Jensen also teaches a protective release covering which is removed upon use (Figure 3, 32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of WO 97/42985 and Jensen and substitute WO's plastic film for Jensen's material. One would be motivated to do so since Jensen teaches a release coating minimizes friction generated during the rolling process. Thus, since WO and Jensen utilize the same rolling process, one would be motivated to use a paper coated with silicone to increase efficacy during the process of making the dressing. Further, one would be motivated to look to Jensen since Jensen teaches a protective release paper before use of the dressing.

Response to Arguments

Applicant argues that WO teaches a hydrophobic gel mixture and the instant invention's gel is a hydrophilic mixture. Applicant argues that WO does not teach using a web with a lower surface energy than the liquid pregel to avoid occlusion. Applicant also argues that Jensen does not teach either. It is further argued that WO does not teach precoating the web.

First the examiner points out that the instantly rejected claims do not recite that the pregel is hydrophilic as argued by the applicant. Therefore, the argument that WO teaches a hydrophobic gel is moot. Further, the plastic film implicitly has a lower surface energy than the pregel mixture since the plastic film is a solid compared to the liquid pregel and thus has a lower

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surface tension. Further, Cheong (US patent 5,352,508) also supports the low surface energy of plastic as a release sheet. See column 5, lines 52-58. However, WO does not teach the instant web material or instant coating. Therefore, the examiner cures this deficiency by relying on Jensen. Jensen teaches the use of a release web is a material with a release coating and exemplifies silicone coated paper. From this teaching alone, Jensen generically teaches the concept of coating a web with a release material. The motivation to coat the web is that it prevents the hydrocolloid (hydrophobic and hydrophilic gel) gel from sticking to the roller and thereby making the rolling process more efficient. The prior art does not have to show all the results obtainable by the disclosed prior art process, i.e. the use of the coated web, it merely has to show that the process is within the skill of the art. Since the prior art shows the instant steps, the process per se is deemed obvious.

Claims 1-6, 9-10, 12-15, 17-18, 24-31, 42, and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofeditz et al (4,552,138).

Hofeditz et al teach a dressing material. The hydrophilic gel is spread onto a release paper (siliconized paper), used as a auxiliary carrier, to provide a thickness of about 0.5-2mm. See column 2, lines 29-36. The hydrophilic gel contains 15-30% water and 15-45% of polyhydric alcohols (plasticizer). The soft mass is then spread on a non-woven fabric or an open-pore foam of polyethylene, polypropylene, polyurethane, or polyester and subjected to the curing process. See example 1 combined with 5-6.

Hofeditz does not specify the reticulation of the liquid pregel along the perforated substrate.

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Although, the prior art does not specify the instant functional limitation, this is deemed obvious to one of ordinary skill in the art at the time the invention was made since the prior art teaches all the instant steps, it is shown that the process steps are within the skill of an artisan and the functional limitations would flow from this teachings. The prior art need not show all the results that flow from the prior art process steps.

Claims 11, 19-20, 22, 32-38, and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofeditz et al (4,552,138) in view of Kundel (5,674,346).

Hofeditz et al teach a dressing material. The hydrophilic gel is spread onto a release paper (siliconized paper), used as a auxiliary carrier, to provide a thickness of about 0.5-2mm. See column 2, lines 29-36. The hydrophilic gel contains 15-30% water and 15-45% of polyhydric alcohols (plasticizer). The soft mass is then spread on a non-woven fabric or an open-pore foam of polyethylene, polypropylene, polyurethane, or polyester and subjected to the curing process. See example 1 combined with 5-6.

The reference does not teach a gel containing acrylate monomer.

Kundel teaches a hydrogel wound dressing. Kundel teaches conventional polymers such as acrylates that form the hydrogel (col. 4, lines 30-40). Further, Kundel teaches the conventional use of a protecting release layer prior to use. See examples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hofeditz et al and Kundel and utilize the instant monomers to formulate the hydrogel. One would be motivated to look to Kundel also teaches hydrophilic wound dressing and teaches the conventional use of acrylates in wound dressing compositions. Therefore, it is deemed obvious to use conventional gel materials to formulate a

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hydrophilic wound dressing. Further, the use of a release layer prior to the use of the wound dressing is an obvious step as taught by the prior art. One would be motivated to protect the gel from bacteria and the environment prior to its use as a wound dressing.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

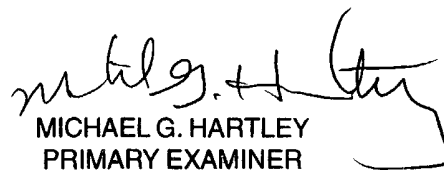
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG


MICHAEL G. HARTLEY
PRIMARY EXAMINER